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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/557,001 04/20/00 GWAG

B 0217-0001

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SHANKS & HERBERT  
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1033 N FAIRFAX STREET SUITE 306  
ALEXANDRIA VA 22314

EXAMINER

ZUCKER, P

ART UNIT

PAPER NUMBER

1623

5

DATE MAILED:

07/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/557,001

Applicant(s)

GWAG ET AL.

Examiner

Paul A. Zucker

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities:

- Page 12, line 1 The phrase "ice chip was" should be changed to "ice chips were". Each occurrence of this phrase should be corrected.
- Page 8, line 1 The acronym "BSA" has been misspelled.
- Page 17, line 29 The acronym "BSO" has not been defined.
- Page 19, line 5 The acronym "BSO" has not been defined.
- Page 4, line 15 The word "distillation" should be changed to "distill".
- Page 5-Page 8 The Brief Description of the Drawings should simply identify the figure and its significance. Detailed discussion of the figures should be placed in the Detail Description of the Invention.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites "suffering from such diseases" in line 3. No diseases, however, are recited. The claim is therefore rendered indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Shen et al (US 3,674,844 07-1972). Shen discloses (Column 1, line 28-Column 2, line 71) a genus of 5-amino-salicylic acid derivatives encompassing the instant claimed genus. Compounds such as 5-(p-fluorobenzylamino) salicylic acid are explicitly exemplified (Example 3, Column 5, lines 50-68). The corresponding para-trifluoromethyl, and para-chloro compounds are disclosed by reference to the general procedure (Example 2, Column 5, lines 29-41). The corresponding benzoyl compounds such as 5-(4-nitrobenzoyl) amino salicylic acid are disclosed as well (Example 1, Column 4, line 60-Column 5, line 16, especially Column 4, line 73). The administration of these compounds is also anticipated (Column 2, line 72-Column 3, line 3) in therapeutically effective amount therefore the instant claimed use as a neuroprotectant is inherently anticipated by the disclosure of Chen.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spector et al (The Journal of Pharmacology and Experimental Therapeutics, 1974 188(2)

pages 55-65) and further in view of Kumamoto et al (Japanese Journal of Pharmacology 1997, 75, pages 187-189) and further in view of Shen et al (US 3,674,844 07-1972). Spector discloses a study of the concentration of para-aminosalicylic acid (PAS) in cerebrospinal fluid. This disclosure teaches that PAS crosses the blood-brain barrier and thus can be expected to reach therapeutically effective concentrations at the target site (page 55-56, whole first paragraph). Kumamoto teaches that aminosalicylates inhibit lipid peroxidation in rat intestinal mucosa after ischemia, resulting from hypoxia, possibly by scavenging the oxygen derived free radicals (Page 187, left column, lines 2-8). PAS (5-ASA according to Kumamoto) inhibited peroxide formation in a dose dependant manner (page 189, left column, line 1). Shen teaches (Column 1, line 28-Column 2, line 71) a genus of 5-amino-salicylic acid derivatives for administration as therapetic compounds(Column 2, line 72-Column 3, line 3) Thus it would have been obvious for one of ordinary skill in the art to have realized that oxidative stress and associated cerebral disease could be treated with the PAS derivatives taught by Shen. The motivation is to provide an improved method of delivering PAS and its derivatives to the target organ. The expectation for success would be high since the administration of these compounds is known.

### ***Conclusion***

5. Claims 1-9 are outstanding. Claims 1-9 are rejected.

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6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Shen et al US PATENT: 3,632,760 01-1972

Discloses 5-aminosalicylic acids and their therapeutic use.

Nussbaumer et al Journal of Medicinal Chemistry 1994, 37, pages 4079-4084

Discloses Lavendustin A derivatives with structures related to the instant 5-aminosalicylic acids and discusses their cellular availability.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist can be reached on 703-308-1701. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

PAZ  
July 20, 2001



GARY GEIST  
SUPERVISORY PATENT EXAMINER  
TECH CENTER 1600